

***United States Court of Appeals
for the Second Circuit***



**PETITION FOR
REHEARING
EN BANC**

ORIGINAL
WITH PROOF
OF SERVICE

75-6109

UNITED STATES COURT OF APPEALS

for the

SECOND CIRCUIT

ELIZABETH DALEY, M.D.,

Plaintiff-Appellant,

-against-

F. DAVID MATTHEWS, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of the Food and Drug Administration, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

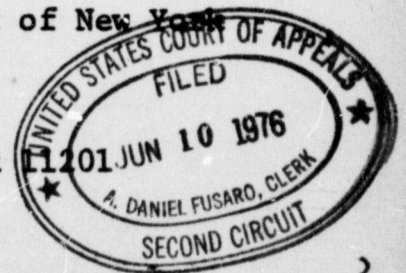
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

PETITION FOR REHEARING AND SUGGESTION
FOR REHEARING IN BANC

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(5531)

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ELIZABETH DALEY, M.D.,

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SCHMIDT, M.D., Commissioner of the
Food and Drug Administration, CLIFFORD
G. SHANE, Regional Director of the
Food and Drug Administration, TERRY
MUSSON, ALLEN R. HALPER, JOHN E.
KLEMMER and THOMAS D. GARDINE,
Employees of the Food and Drug
Administration,

Defendants-Appellees.

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FOR THE EASTERN DISTRICT OF NEW YORK

PETITION FOR REHEARING AND SUGGESTION
FOR REHEARING IN BANC

Preliminary Statement

Appellant Elizabeth Daley, M.D., respectfully petitions for rehearing, and suggests rehearing in banc, of the decision of this Court (Medina, Feinberg and Gurfein, J.J.), filed May 27, 1976, affirming the order of the district court which dismissed the complaint on the ground that a controversy sufficiently ripe for adjudication does not exist between the parties.

Argument

Following a second attempt by Food and Drug Administration ("FDA") inspectors to conduct a warrantless, administrative search of her medical office, appellant Elizabeth Daley, M.D., commenced this action for declaratory and injunctive relief against further FDA interference with her medical practice, claiming that the FDA lacks statutory authority under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301, et seq., to inspect or otherwise enforce the provisions of the Act against a duly-licensed physician engaged in the lawful practice of medicine. The district court, upon motion of the FDA, entered summary judgment dismissing the complaint on the ground that the controversy was not sufficiently ripe for adjudication. On May 27, 1976, this Court affirmed.

The fundamental issue raised in this appeal is whether a federal agency may effectively insulate itself from judicial review by simply retreating whenever a citizen against whom it has taken unlawful administrative action seeks to challenge the agency's authority in federal court, thereby eliminating the jurisdictional prerequisite of an actual case or controversy. This is precisely what has occurred here and unfortunately been condoned by the Court's decision.

In affirming dismissal of the complaint for lack of ripeness, the Court viewed this case as a "pre-enforcement" challenge to agency action*. If this were correct, that is, if the FDA had never attempted to enforce the challenged statute--Section 704 of the Food and Drug Act--against appellant, then she would have little cause to complain. But this is simply not the case.

*At page 3944 of the slip opinion, the Court wrote:
In a trilogy of decisions.... the Supreme Court made clear that in assessing the fitness for review of challenges to pre-enforcement agency action (emphasis added).

and,

... Seemingly [appellant's] situation is more closely analagous to that in Toilet Goods Assn., Inc. v. Gardner, supra, where the Court found that "consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations." 387 U.S. at 171 [footnote omitted].

FDA inspectors first served a notice of inspection and attempted to search appellant's medical office on February 10, 1975. They were refused entry and referred to appellant's attorneys. For approximately two weeks thereafter, there were several communications between appellant's counsel and FDA officials, during which appellant offered to cooperate with the FDA (in their apparent investigation of drugs she was administering to her patients) in any reasonable manner other than through an unauthorized "factory inspection" of her medical office. FDA's ultimate response was to reject this offer, and to serve a second notice and attempt another inspection on February 27, 1975. Of course, FDA knew full well, having spoken to appellant's lawyer just two days prior, that they would again be denied entry to appellant's office for purposes of such an inspection. The very next day, February 28, 1975, fearing what further action the FDA might take against her, appellant commenced this lawsuit for declaratory and injunctive relief.

It is thus quite clear that this is not a "pre-enforcement" situation. This action was filed only after the FDA not once, but twice, attempted to enforce the factory inspection statute [21 U.S.C. §374(a)] against appellant. A ripe controversy existed at that time, and subsequent representations of FDA should not be permitted to defeat it.

The Court is of course aware, and has indeed outlined in its opinion, the several alternative courses of action which the FDA can now take against appellant, as well as the other adverse consequences of FDA's action against her. (Slip Op. 3943). These include possible criminal prosecution under 21 U.S.C. §331(f) for refusing to permit entry or inspection pursuant to Section 704, or causing such refusal.

In Abbott Laboratories v. Gardner, 387 U.S. 136, (1967), where drug manufacturers challenged FDA regulations, a somewhat similar situation arose. There, as here, non-compliance with the challenged enactment carried criminal sanctions, but the government represented that no criminal prosecution would be brought. In holding the controversy ripe for adjudication, the Court said:

The Government further contends that the threat of criminal sanctions for noncompliance with a judicially untested regulation is unrealistic; the Solicitor General has represented that if the court enforcement becomes necessary, "The Department of Justice will proceed only civilly for an injunction ... or by condemnation." We cannot accept this argument as a sufficient answer to petitioners' petition. This action at its inception was properly brought and this subsequent representation of the Department of Justice should not suffice to defeat it.

327 U.S. at 154.

The Supreme Court, and in the past this Court, have recognized the unique sensitivity of the medical profession, and have not required a physician to risk criminal prosecution in order to raise a good faith challenge to government interference with the practice of his profession. See Doe v. Bolton, 410 U.S. 179, 188 (1973); Abele v. Markle, 452 F.2d 1121, 1125 (2d Cir. 1971). Cf. Gardner v. Toilet Goods Association, 387 U.S. 167, 172 (1967). Yet this is precisely the situation in which appellant has now been left.

Conclusion

For the foregoing reasons, this petition should be granted, and the judgment of the district court reversed.

Respectfully submitted,

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STATE OF NEW YORK)
COUNTY OF NEW YORK) ss.:

Robert E. Egan, being duly sworn,
deposes and says that deponent is not a party to the action,
is over 18 years of age and resides at 385 Kensington St. Brooklyn

That on the 10 day of JUNE, 1976,
deponent personally served the within PETITION FOR REHEARING
AND SUGGESTION FOR REHEARING IN BANC
upon the attorneys designated below who represent the
indicated parties in this action and at the addresses below
stated which are those that have been designated by said
attorneys for that purpose.

By leaving 2 true copies of same with a duly
authorized person at their designated office.

~~By depositing true copies of same enclosed
in a postpaid properly addressed wrapper, in the post office
or official depository under the exclusive care and custody
of the United States post office department within the State
of New York.~~

Names of attorneys served, together with the names
of the clients represented and the attorneys' designated
addresses.

DAVID G. TRAGER
UNITED STATES ATTORNEY FOR THE
EASTERN DISTRICT OF NEW YORK
ATTORNEY FOR DEFENDANTS - APPELLEES
By CYRIL HYMAN
ASSISTANT U.S. ATTORNEY
225 CADMAN PLAZA EAST
BROOKLYN, N.Y. 11201

Sworn to before me this

10th day of June

Robert E. Egan
1976
Michael DeSanti

MICHAEL DE SANTIS
Notary Public, State of New York
No. 03-0930908
Qualified in Bronx County
Commission Expires March 30, 1977